NDA 21-906, KALETRA® (lopinavir/ritonavir) Tablets

NDA 21-251, KALETRA® (lopinavir/ritonavir) Oral Solution

Class of Product: HIV-1 Protease Inhibitor

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RISK EVALUATION AND MITIGATION STRATEGY (REMS)

I. Goals

The goal of the REMS is to inform patients of the serious risks associated with the use of Kaletra, including the risk of potential cardiac arrhythmias.

II. REMS Elements

A. Medication Guide

A Medication Guide will be dispensed with each Kaletra Tablet and Kaletra Oral Solution prescription. Kaletra Tablets and Kaletra Oral Solution are sold in unit of-use packaging whereby the approved U.S. package insert containing the Medication Guide will be included with each unit-of-use package. This will permit the authorized dispenser to provide a Medication Guide to each patient receiving a prescription for Kaletra. In addition, the Kaletra package insert containing the Medication Guide will be made available via the internet at www.KALETRA.com.

Additionally, in accordance with 21 CFR §208.24(d), the Kaletra Tablet container labels and the Kaletra Oral Solution carton and container labels will alert pharmacists to dispense the Medication Guide with the product.

B. Timetable for Submission of Assessments

Abbott will submit REMS Assessments to the FDA by 18 months, 3 years, and 7 years from the date of the approval of the REMS. To facilitate inclusion of as much information as possible while allowing reasonable time to prepare the submission, the reporting interval covered by each assessment should conclude no earlier than 60 days before the submission date for that assessment. Abbott will submit each assessment so that it will be received by the FDA on or before the due date.

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/s/

KENDALL A MARCUS
02/24/2011